REMARKS

In response to the rejections raised in the February 24, 2003 Office Action, our comments follow. Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 23-26, 29-32 and 34-36 are pending in this application. Claims 23-26, 29-32 and 34-36 have been amended; claims 27, 28 and 33 have been cancelled. Support for the amended claims is found throughout the specification. No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Restriction Requirement

In the Amendment filed on May 6, 2002, the claims were inadvertently amended to recite "rice", rather than the intended "*Brassica*". In the Amendment filed November 19, 2002 the recitation of 'rice' in claim 29 instead of 'Brassica' was inadvertently not corrected. Applicants correct this mistake with entry of the present Amendment and request consideration thereof.

Claims 29-32 had been withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Applicants request entry of the present amendment and submit that the amendment renders claims 29-32 part of elected Group I. The Examiner argued in paper 15 that the method of Group I (claims 23-28 and 33-34) may be practiced with a materially different product, and that the product of Group II (claims 29-32) may be independently used in a materially different process such as a diagnostic process unrelated to the diagnostic process of plants of the invention of Group I.

Applicants respectfully submit that, with the entry of the present Amendment, the kits of claims 29-32 can only be used in a diagnostic process of plants of the invention of Group I,

namely on *Brassica* plants which comprise bases 1-234 of SEQ ID NO:8 or bases 194-416 of SEQ ID NO:10 in their genome. Applicants therefore request that claims 29-32 be rejoined in this application.

Claim Objections

Claims 23-27 and 31-36 were objected to because of informalities. Applicants have replaced all instances of "SEQ ID No." with "SEQ ID NO:". In claims 25-26, the comma following "SEQ ID No. 8" was objected to. Amendment of claims 25-26 renders this objection moot. Withdrawal of these objections is respectfully requested.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

Enablement

Claims 23-28 and 33-36 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The Office Action argued that the application does not provide enablement for a method of identifying elite event MS-B2 in transgenic *Brassica* or confirming seed purity using PCR with any primer or using any hybridization method.

The claims have been amended to replace "5' flanking region of SEQ ID No. 8" with "bases 1-234 of SEQ ID NO:8" and "3' flanking region of SEQ ID No. 10" with "bases 194-416 of SEQ ID NO:10". They have also been amended to replace "foreign DNA" with "SEQ ID NO:1", and "recognizes" with "hybridizes to". In as far as the rejection still applies to the amended claims, it is respectfully traversed.

Once a nucleotide sequence is disclosed, a skilled person can easily design and make primers or probes which hybridize to the nucleotide sequence, and which can be used in PCR or Southern analysis. Applicants therefore submit that a skilled person can easily design PCR primers or probes which hybridize to bases 1-234 of SEQ ID NO:8, or to bases 194-416 of SEQ ID NO:10 or to SEQ ID NO:1 using known methods, such as described in standard molecular biology manuals. For example, Plant Molecular Biology Labfax by Croy (cited in the application), Chapter 10, lists references and computer programs which can be used for primer design. Similarly, Molecular Cloning - A Laboratory Manual, Second edition (Sambrook et al; cited in the application), Section 14, deals with "in vitro amplification of DNA by the Polymerase Chain Reaction" and Chapter 11 deals with "Synthetic Oligonucleotide Probes".

Applicants therefore submit, that the specification does not only provide guidance to primers with SEQ ID NOs: 4-17, 9 and 11-14, but to any primer or probe which hybridizes to bases 1-234 of SEQ ID NO:8, or to bases 194-416 of SEQ ID NO:10 or to SEQ ID NO:1.

The Office Action further purports that the instant specification fails to teach the "MS-B2 PCR Identification Protocol". Although cancellation of claims 27-28 renders this objection moot, note that the MS-B2 PCR Identification Protocol is taught in Example 5.2. entitled "MS-B2 Elite Event Polymerase Chain Reaction identification Protocol".

The rejection of claims 33 and 35, based on the allegation that the specification does not teach how the failure to detect an MS-B2 specific region in a batch of seed will confirm purity of the entire batch, is overcome by the present claim amendments, i.e. cancellation of claim 33 and amendment of claim 35 to recite "A method for screening the genomic DNA of seeds for the absence of MS-B2".

Written Description

Claims 23-28 and 33-36 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The present claim amendments overcome this rejection, as specific nucleotide sequences are recited. In as far as the rejection still applies to the amended claims, it is respectfully traversed.

As explained above, the specification describes specific sequences (bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10 and SEQ ID NO:1) and a number of primers and probes, which specifically hybridize to said sequences, such as, for example, SEQ ID NO: 4-7, SEQ ID NO:9, SEQ ID NO:11 and SEQ ID NO:12. It is easy for a skilled person to generate additional primers and probes which hybridize to the specific sequences using the known methods referred to above. For example, almost any stretch of e.g. 20 nucleotides identical or complementary to a contiguous stretch of 20 nucleotides of bases 1-234 of SEQ ID NO:8 or bases 194-416 of SEQ ID NO:10 would be a suitable primer to use in the claimed methods or kits.

Applicants need not have <u>physical</u> possession of each and every primer and probe encompassed by the claims, as these can be readily determined by those skilled in the art. Applicants submit that each and every primer and probe encompassed by the claims could be written out by one skilled in the art with only the specification as a reference and could be

generated and used in the claimed method. Further, the structural features that distinguish the encompassed primers and probes from other nucleic acids are clearly delimited by the requirement that the primers or probes hybridize to bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10 or SEQ ID NO:1.

The Office Action refers to *Univ. of California v. Eli Lilly* (Fed. Circ. 1997). It is submitted that this case is not applicable to the instant application, as in *Univ. of California* the DNA sequences were lacking, while in the instant application the DNA sequences are provided. The instant application is therefore also fully compliant with *Amgen Inc. v Chugui Pharmaceutical Company*, cited in the Office Action, as the instant invention does provide the 'structure of the chemical' by providing the specific nucleotide sequences.

In view of the amendments and arguments submitted herein, reconsideration and withdrawal of the §112, first paragraph, rejections are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 23-28 and 33-36 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

In claims 23-26 and 33-36, the recitation of "5' flanking region of SEQ ID NO:8" has been changed to "bases 1-234 of SEQ ID NO:8" and the recitation of "3' flanking region of SEQ ID NO:10" has been changed to "bases 194-416 of SEQ ID NO:10", as suggested by the Examiner.

Claim 23 has been amended to use the gerund form of the verb. Claims 23 and 33-36 were rejected on the basis that it is unclear in what detection occurs. Claims 23 and 34-36 have been amended to clarify that detection refers to detection in the DNA of a specific region.

"Specifically recognizes" in claim 23 and "recognizes" in claims 24-26 and 36 have been replaced by "hybridizes", obviating the rejection on this basis.

Regarding claim 25, the Examiner asked whether it contained an unnecessary repetition. The Examiner is thanked for pointing to this deficiency, and claim 25 has been amended to correct it.

Claim 24 has been amended to recite "SEQ ID NO:1", rather than the "the foreign DNA". Claim 24 has also been amended to clarify that the detection step follows the amplification step, and that the detection step occurs by detecting the amplified DNA on an

agarose gel. Further, it is clear that the primers are used in the amplification step of the PCR reaction, prior to the detection.

Cancellation of claim 27 and 28 renders the rejections of these claims moot.

Claims 33-35 were rejected by the Examiner as being indefinite in their recitation of "specifically hybridizing". Cancellation of claim 33 renders the rejection moot with respect to that claim. Deletion of "specifically" in claims 34 and 35 overcomes this rejection.

Claim 35 was rejected as failing to recite active method steps. Applicants have amended claim 35 to recite active, positive method steps.

Claim 36 has been amended to recite "performing a polymerase chain reaction", rather than "using a polymerase chain reaction". It is submitted that it is not necessary to recite each step involved in carrying out a PCR reaction, as these steps are well known in the art and are described, e.g. in Example 5.2 (preparation of the PCR reaction mixture containing template DNA, primers, dNTPs, polymerase, etc., and placing the reactions in a PCR thermal cycler).

Reconsideration and withdrawal of all of the rejections under §112, second paragraph, are requested.

IV. DOUBLE PATENTING

Claims 23-26 and 34 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-8 of U.S. Patent No. 6,509,516. The Examiner is thanked for agreeing to hold the rejection in abeyance.

Applicants wish to point out that claims 1-8 of U.S. Patent No. 6,509,516 are drawn to "plants", which are product claims, while claims 23-26 and 34 are "method" claims. A product is a different subject matter than a method.

Claims 27 and 28 were rejected under 35 U.S.C. §101 as claiming the same invention as claims 9 and 10 of U.S. Patent No. 6,509,516. Claims 27 and 28 have been cancelled, obviating this rejection.

Reconsideration and withdrawal of the double patenting rejections are requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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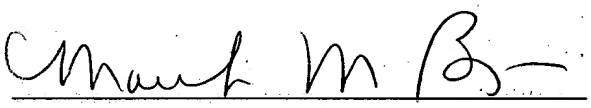
By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

23. (Thrice Amended) A method for identifying elite event MS-B2 in a transgenic *Brassica* plant, or cell or tissue thereof, or transgenic *Brassica* plant material, which method comprises [detection of] detecting in the DNA of said plant, cell, tissue or material a MS-B2 specific region with a specific primer or probe which [specifically recognizes the 5' flanking region in] hybridizes to bases 1-234 of SEQ ID [No.]NO:8 or [the 3' flanking region in]to bases 194-416 of SEQ ID [No.]NO:10 of MS-B2.

24. (Thrice Amended) The method of claim 23, said method comprising amplifying a DNA fragment of between 160 and 200 by from a nucleic acid present in said transgenic *Brassica* plant, or cell or tissue thereof, or transgenic *Brassica* plant material, using a polymerase chain reaction with at least two primers, one of which [recognizes the 5' flanking region in]hybridizes to bases 1-234 of SEQ ID [No.]NO:8 or [3' flanking region in]to bases 194-416 of SEQ ID [No.]NO:10 of MS-B2, the other of which [recognizes]hybridizes to a sequence within [the foreign DNA]SEQ ID NO:1, and detecting said amplified DNA fragment on an agarose gel.

25. (Amended) The method of claim 24, wherein one of said primers [recognizes a sequence within the 5' flanking region of SEQ ID No. 8, and the other recognizes a sequence within the foreign DNA]hybridizes to a sequence within SEQ ID NO:1 and comprises the sequence of SEQ ID NO:12.

26. (Amended) The method of claim [25]24, wherein one of said primers [recognizing a sequence within the 5'flanking region of SEQ ID No. 8,]hybridizes to bases 194-416 of SEQ ID NO:10 and comprises the sequence of SEQ ID [No.]NO:11.

29. (Twice Amended) A kit for identifying elite event MS-B2 in a transgenic [rice]*Brassica* plant, or cell or tissue thereof, or transgenic [rice]*Brassica* plant material, said kit comprising at least one PCR primer, which [recognizes a sequence within the 5' flanking region in]hybridizes to bases 1-234 of SEQ ID [No.]NO:8 or [the 3' flanking region in]to bases 194-416 of SEQ ID [No.]NO:10 of MS-B2.

30. (Amended) The kit of Claim 29, which further comprises at least a second PCR primer which [recognizes a sequence within the foreign DNA]hybridizes to a sequence within SEQ ID NO:1 of MS-B2.

31. (Amended) The kit of claim 30, wherein said [at least one] PCR primer [recognizes a sequence within the 5' flanking region of SEQ ID No. 8]comprises the sequence of SEQ ID NO:12.

32. (Amended) The kit of claim [31]29, wherein said at least one PCR primer comprises the sequence of SEQ ID [No.]NO:11.

34. (Twice Amended) A method for screening the genomic DNA of seeds for the presence of MS-B2, which method comprises detecting an MS-B2 specific region comprising the insertion site of MS-B2 with a specific primer or probe which [specifically] hybridizes to [the 5' flanking region]bases 1-234 of SEQ ID [No.]NO:8 or [the 3' flanking region]to bases 194-416 of SEQ ID [No.]NO:10 of MS-B2, and thus confirming the presence of MS-B2 if the MS-B2 specific DNA sequence is so detected in samples of seed lots.

35. (Amended) A method for [confirming seed purity]screening the genomic DNA of seeds for the absence of MS-B2, which method comprises carrying out a Polymerase Chain Reaction or Southern Blot[not detecting an MS-B2 specific DNA sequence] using a specific primer or probe which [specifically] hybridizes to [the 5' flanking region]bases 1-234 of SEQ ID [No.]NO:8 or [the 3' flanking region]to bases 194-416 of SEQ ID [No.]NO:10 of MS-B2, and not detecting the presence of MS-B2 specific DNA on an agarose gel or Southern Blot membrane, thus confirming the absence of MS-B2 in said seeds[seed purity, if the MS-B2 specific DNA is not so detected].

36. (Amended) A method for identifying a *Brassica* plant, or cell or tissue thereof, or *Brassica* plant material not comprising elite event MS-B2, which method comprises [establishing whether a DNA fragment of between 160 and 200 base pairs cannot be amplified from the genomic DNA of the plant, cell, tissue or plant material, using]performing a polymerase chain reaction with at least two primers, one of which recognizes [the 5' flanking region]bases 1-234 of SEQ ID [No.]NO:8 or [the 3' flanking region]bases 194-416 of SEQ ID [No.]NO:10 of MS-B2, another of which recognizes a sequence within [foreign DNA,]SEQ ID NO:1, [which method amplifies a DNA fragment of between 160 and 200 base pairs from DNA comprising elite event MS-B2]and detecting the absence of a DNA fragment of between 160 and 200 base pairs on an agarose gel.